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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/581,718	06/22/2006	Denis Claude Roy	029049.57806US	8573

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EXAMINER	
JUEDES, AMY E	

ART UNIT	PAPER NUMBER
1644	

NOTIFICATION DATE	DELIVERY MODE
11/13/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ADIPFDD@bipc.com

Office Action Summary	Application No.	Applicant(s)	
	10/581,718	ROY ET AL.	
	Examiner	Art Unit	
	AMY E. JUEDES	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 July 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *49-83* is/are pending in the application.

4a) Of the above claim(s) *53-81* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *49-52 and 82-83* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's amendment and remarks, filed 7/1/09, are acknowledged.

Claim 49 has been amended.

Claims 82-83 have been added.

Claims 49-83 are pending.

Claims 53-81 stand withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Claims 49-52 and 82-83 are being acted upon.

2. Claim 83 is objected to for the following informalities: The claims recites the phrase "wherein the vaccine" twice. Correction is required.

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 49-52 stand rejected under 35 U.S.C. 102(b) as being anticipated by Brasseur et al., 2000, Photochem. and Photobiol (of record).

As set forth previously, Brasseur et al. teach a composition comprising PDT treated tumor cells. Brasseur et al. teach treating the cells with the photosensitizer 4,5-dibromorhodamine methyl ester (TH9402), i.e. the compound of formula I. Brasseur et al. teach activating the compound by exposing the cells to light centered around 515 nm (see page 781, in particular). Furthermore, the recitation of an "immunologic vaccine" refers to an intended use of the claimed PDT-treated cells, and does not carry patentable weight in the absence of a structural difference. The PDT treated cells of Brasseur et al. are structurally identical to the PDT treated cells of the instant claims.

Applicant's arguments filed 7/1/09 have been fully considered, but they are not persuasive.

Applicant argumues that a vaccine is a composition that induces an immune response and typically comprises attenuated or dead antigens and a pharmaceutically acceptable carrier. Thus, Applicant concludes that the active component of the instant

claims are dead cells. Applicant argues that Brasseur does not disclose an immunologic vaccine comprising dead cells, as claimed, but rather a composition of living cells.

The instant claims are drawn to a vaccine comprising PDT treated cells, and are not necessarily limited to dead cells, as asserted by Applicant. For example, as conceded by Applicant, vaccines can comprise attenuated (i.e. live) antigens. Regardless, Brasseur et al. teach that the PDT/light treatment results in the eradication (i.e. the death) of the tumor cells in the composition (see page 783, in particular). Thus, the cell compositions of Brasseur et al. comprise dead tumor cells. Furthermore, Brasseur et al. teach that the cells are suspended in tissue culture medium (i.e. a pharmaceutically acceptable carrier). Therefore, the cell compositions of Brasseur et al. are structurally identical to those of the instant claims and would inherently be capable of acting as a vaccine to induce an immune response (i.e. the intended use of the claimed invention). If a prior art structure is capable of performing the intended use as recited in the preamble, then it meets the claim. See, e.g., In re Schreiber, 128 F.3d 1473, 1477, 44 USPQ2d 1429, 1431 (Fed. Cir. 1997) and MPEP 2112.02.

5. Claims 49-52 stand rejected under 35 U.S.C. 102(b) as being anticipated by Roy et al., 2000, Blood.

As set forth previously, Roy et al. teach a composition comprising PDT treated blood stem cells. Roy et al. teach treating the cells with the photosensitizer TH9402 (i.e. the compound of formula I, which is inherently a compound activatable by light having a wavelength of about 450 to 600nm). Furthermore, Roy et al. teach administering the PDT treated cells to a cancer subject (i.e. an "immunologic vaccine").

Applicant's arguments filed 7/1/09 have been fully considered, but they are not persuasive.

Applicant argues that a vaccine is a composition that induces an immune response and typically comprises attenuated or dead antigens and a pharmaceutically acceptable carrier. Thus, Applicant concludes that the active component of the instant claims are dead cells. Applicant argues that Roy et al. do not disclose an immunologic vaccine comprising dead cells, as claimed, but rather a composition of living cells.

The instant claims are drawn to a vaccine comprising PDT treated cells, and are not necessarily limited to dead cells, as asserted by Applicant . For example, as conceded by Applicant, vaccines can comprise attenuated (i.e. live) antigens. Regardless, Roy et al. teach that the TH9402 is highly cytotoxic to leukemia cells present in the cell composition. Thus, the TH9402 treated cell compositions of Roy et al. comprise dead leukemia cells. Furthermore, Roy et al. teach administering the cell compositions to patients (i.e. the cell compositions comprise a pharmaceutically acceptable carrier). Thus, the cell compositions of Roy et al. are structurally identical to those of the instant claims and would inherently be capable of acting as a vaccine to induce an immune response (i.e. the intended use of the claimed invention). If a prior art structure is capable of performing the intended use as recited in the preamble, then it meets the claim. See, e.g., In re Schreiber, 128 F.3d 1473, 1477, 44 USPQ2d 1429, 1431 (Fed. Cir. 1997) and MPEP 2112.02.

6. Claims 49-52 stand rejected under 35 U.S.C. 102(b) as being anticipated by WO 01/24824 (of record).

As set forth previously, WO 01/24824 teaches a composition comprising cells treated with a photoactivatable compound of formula I. WO 01/24824 teaches activating said compound with light of a wavelength of around 512 nm (see pages 10-11 and 21, in particular). WO 01/24824 also teaches administering the PDT cells to treat immunologic disorders (i.e. an "immunologic vaccine", see pages 10-11, in particular).
Applicant's arguments filed 7/1/09 have been fully considered, but they are not persuasive.

Applicant argues that a vaccine is a composition that induces an immune response and typically comprises attenuated or dead antigens and a pharmaceutically acceptable carrier. Thus, Applicant concludes that the active component of the instant claims are dead cells. Applicant argues that WO 01/24824 do not disclose an immunologic vaccine comprising dead cells, as claimed, but rather a composition of living cells.

The instant claims are drawn to a vaccine comprising PDT treated cells, and are not necessarily limited to dead cells, as asserted by Applicant. For example, as conceded by Applicant, vaccines can comprise attenuated (i.e. live) antigens. Regardless, WO 01/24824 teaches that the compound/light treatment of the cell

compositions results in destruction (i.e. death) of cells in the composition (see page 10 in particular). Furthermore, WO 01/24824 teaches administering the cell compositions to patients (i.e. the cell compositions comprise a pharmaceutically acceptable carrier). Thus, the cell compositions of WO 01/24824 are structurally identical to those of the instant claims and would inherently be capable of acting as a vaccine to induce an immune response (i.e. the intended use of the claimed invention). If a prior art structure is capable of performing the intended use as recited in the preamble, then it meets the claim. See, e.g., In re Schreiber, 128 F.3d 1473, 1477, 44 USPQ2d 1429, 1431 (Fed. Cir. 1997) and MPEP 2112.02.

7. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 49-52 stand provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 25 of copending Application No. 10/969,011. As set forth previously, Although the conflicting claims are not identical, they are not patentably distinct from each other because the '011 application claims treating hematopoietic cells with a photoactivatable compound of formula I, irradiating the cells with a light of suitable wavelength, (i.e. PDT treated cells). The '011 application also claims administering the cells to a patient as a stem cell transplant (i.e. an "immunologic vaccine").

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Applicant's arguments filed 7/1/09 have been fully considered, but they are not persuasive.

Applicant argues that the '011 application was filed after the instant application, and since the claims of the instant application are allowable, the obviousness type double patenting rejection should be withdrawn.

However, the instant claims are not allowable and the obviousness type double patenting rejection is therefore maintained.

8. The following are new grounds of rejection necessitated by Applicant's amendment. It is noted that new claims 82-83 are dependent from independent claim 49. Therefore, claim 49 is being included in the rejection below, since a dependent claim by definition includes the limitations of the independent claim from which it depends and further limits the independent claim.

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to

a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 49 and 82-83 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gollnick et al., March 2003, in view of Sharman et al., 1999.

Gollnick et al. teach a tumor cell lysate immunologic vaccine consisting of the supernatant from PDT treated tumor cells (see page 1604, in particular). Gollnick et al. teach producing the cell lysate by treating tumor cells with photoforin (i.e. a photoactivatable compound) activating the cells with light (see page 1604, in particular), and separating and collecting the cell supernatant. Gollnick et al. also teach a composition comprising non-PDT treated dendritic cells and said tumor cell lysate/supernatant from the PDT treated cells (see page 1606, in particular). Gollnick et al. teach that the dendritic cell/lysate composition is suspended in tissue culture medium (i.e. a pharmaceutically acceptable carrier, see page 1605, in particular). Thus, the dendritic cell composition is structurally identical to the "vaccine" of the instant claims.

Gollnick et al. do not teach a photoactivatable compound of formula I.

Sharman et al. teach many types of photoactivatable compounds, including photoforin and TH9402 (i.e. the compound of formula I of the instant claims, see page 4 of the instant specification which discloses said compound is TH9402). Sharman et al. teach that photoforin is a first generation photoactivatable compound that has some disadvantages in that it is not chemically pure and is not exclusively taken up by target tumor tissues (see page 510 in particular). In contrast, Sharman et al. teach that second generation photoactivatable compounds such as TH9402 are chemically pure

compounds that are selective for disease tumor cells while sparing healthy cells (see page 515, in particular). Additionally, Sharman et al. teach that TH9402 is particularly suited for ex-vivo photodynamic applications involving the destruction of malignant cells (see page 515, in particular).

Therefore, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to use TH9402, as taught by Sharman et al., for making the PDT treated tumor cell supernatant vaccines of Gollnick et al. The ordinary artisan at the time the invention was made would have been motivated to do so, since Sharman et al. teach that second generation photoactivatable compounds such as TH9402 are advantageous in that the are chemically pure and are selective for tumor cells while sparing healthy cells. Furthermore, the ordinary artisan would have had a reasonable expectation of success in using TH9402, since Sharman et al. teach that it is particularly suited for ex-vivo photodynamic applications involving destruction of malignant cells. Moreover, selecting from the known photoactivatable compounds (such as those taught by Sharman et al.) would involve choosing among a finite number of predictable options which could be pursued with a reasonable expectation of success. A person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense (see *KSR International Co. V. Telefex Inc* 82 USPQ2d 1385).

10. No claim is allowed.

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy E. Juedes, whose telephone number is 571-272-4471. The examiner can normally be reached on 7am to 3:30pm, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on 571-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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